DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ENTRA HEALTH SYSTEMS
RICHA PADHYA
RAQA COORDINATOR
3111 CAMINO DEL RIO NORTH
SUITE 101
SAN DIEGO CA 92108

January 8, 2016

Re: K143169
Trade/Device Name: MyGlucoHealth Wireless System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: December 3, 2015
Received: December 11, 2015

Dear Richa Padhya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143169

Device Name
MyGlucoHealth Wireless System

Indications for Use *(Describe)*
The MyGlucoHealth Wireless System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of glucose control. The system is comprised of the MyGlucoHealth Wireless Meter, MyGlucoHealth Control Solutions and MyGlucoHealth Wireless Test Strip. The system is intended to be used for the quantitative measurement of glucose (sugar) in whole blood samples drawn from the fingertip, ventral palm, hand,upper arm, forearm, calf and/or thigh. The MyGlucoHealth Wireless Meter is intended to be used by a single patient and should not be shared. The MyGlucoHealth Wireless System is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternate site testing should be done during steady-state times (when glucose is not changing rapidly).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date: September 1 2015

510(k) Summary

A. Submitter: Entra Health Systems

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E. Submission Contact: Richa Padhya - Quality
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F. Trade Name: MyGlucoHealth Wireless System

G. Predicate Device(s): MyGlucoHealth Glucose Monitoring System,
Model MGH-BT1,
Entra Health Systems (K081703)

H. Common Name: Glucose Test System

I. Classification: Class II

Regulation Number	Product Code	Classification Name	Device Class
862.1345	NBW	Glucose Test System	II
862.1345	CGA	Glucose Oxidase, Glucose	II

J. Device Description

The MyGlucoHealth Wireless System comprised of the MyGlucoHealth Wireless Meter, MyGlucoHealth Control Solutions and MyGlucoHealth Wireless Test Strip. The MyGlucoHealth Wireless Meter is different from the MyGlucoHealth Blood Glucose Meter (MGH-BT1) only by the way the glucose data is transferred to the data repository. An embedded cellular module within the meter enables Wireless communication between the meter and the Entra Health Systems remote database called MyHealthPoint TeleHealth Manager (K132930).

The test strip (proprietary to the MyGlucoHealth Wireless Meter) is used only with the MyGlucoHealth Wireless Meter. It is for the quantitative measurement of the concentration of glucose in whole blood that can be taken from the fingertip, ventral palm, dorsal hand,

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upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. The results obtained are plasma calibrated to allow for easy comparison to the laboratory method. The MyGlucoHealth Wireless System is not to be used for the diagnosis of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

K. Intended Use

The MyGlucoHealth Wireless System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of glucose control. The system is comprised of the MyGlucoHealth Wireless Meter, MyGlucoHealth Control Solutions and MyGlucoHealth Wireless Test Strip. The system is intended to be used for the quantitative measurement of glucose (sugar) in whole blood samples drawn from the fingertip, ventral palm, hand, upper arm, forearm, calf and/or thigh. The MyGlucoHealth Wireless Meter is intended to be used by a single patient and should not be shared. The MyGlucoHealth Wireless System is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternate site testing should be done during steady-state times (when glucose is not changing rapidly).

L. Predicate Device(s)

L.1 MyGlucoHealth Wireless System is substantially equivalent to the following FDA cleared predicate device:

Predicate #1

510(k) Number:	K081703
Trade Name:	MyGlucoHealth Glucose Monitoring System
Manufacturer:	**Entra Health Systems**
Common/Usual Name:	Glucose Test System
Regulation Number:	862.1345
Product Codes:	NBW
Classification:	II

M. Substantial Equivalence

Feature	Predicate device MyGlucoHealth MGH-BT1	Candidate Device MyGlucoHealth Wireless MGH-CL1
Intended Use	The MyGlucoHealth glucose monitoring system provides a quick and easy way for diabetic patients to measure and self-monitor blood glucose levels. The system is comprised of the MyGlucoHealth Bluetooth meter (MGH-BT1 w/Bluetooth Wireless download capability) or the MGH-1 (w/o Bluetooth) blood glucose meter, control solution and test strips that carry a biosensor used for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the	The MyGlucoHealth Wireless System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of glucose control. The system is comprised of the MyGlucoHealth Wireless Meter, MyGlucoHealth Control Solutions and MyGlucoHealth Wireless Test Strip. The system is intended to be used for the quantitative measurement of glucose (sugar) in whole blood samples drawn from the fingertip,

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	fingertip, ventral palm, hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. The results obtained are plasma calibrated to allow for easy comparison to the laboratory method. Further, results from either meter may be uploaded to a memory device through a standard RS32 connection, or, with the –BT1 model, Wirelessly transmitted to a Bluetooth capable PC or Cell phone. The MyGlucoHealth glucose monitoring systems are not to be used for the diagnosis or screening of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.	ventral palm, hand, upper arm, forearm, calf and/or thigh. The MyGlucoHealth Wireless Meter is intended to be used by a single patient and should not be shared. The MyGlucoHealth Wireless System is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternate site testing should be done during steady-state times (when glucose is not changing rapidly).
Control solution	Single (Specified) Analyte Controls (Assayed And Unassayed)	Same as Predicate device
Test strips	Glucose Oxidase	Same as Predicate device
Test range	10~600 Mg/dL	Same as Predicate device
Hematocrit Range	20~60%	Same as Predicate device
Test time	3 sec	Same as Predicate device
Sample Volume	0.3 uL	Same as Predicate device
Operating Temp & Humidity Range	50~104°F 10~40°C 10~90%	Same as Predicate device
Speaking Function	No	Same as Predicate device
Test Strip Open use time	3 months	Same as Predicate device
Coding	Coding	Same as Predicate device
Memory capability	250 readings	Same as Predicate device
Day Averages	7, 14, 21-day average	Same as Predicate device
Battery	Two Triple A's	Lithium Ion Battery
Battery Life	2,000 tests	Rechargeable
Size (LxWxH)	52.2 x 98.5 x 23.4 mm	53 x 102 x 20.5 mm
Weight	74.5g (2.5 oz.) with battery	87g (3.06 oz.) with battery
Warranty	2 years	Same as Predicate device
Software	MyHealthPoint TeleHealth Manager (K132930)	Same as Predicate device
Data transferring capability	MGH-BT1 adds Wireless uploading to Bluetooth paired PC, USB cord or cell phone	MCH-CL1 uploads through a cellular radio
Technological Characteristics	The MyGlucoHealth Bluetooth meter (MGH-BT1) consists of a glucose meter	The MyGlucoHealth Wireless Meter consists of a glucose meter that can

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	that can Wirelessly transmit data to a remote database using standard Bluetooth technology embedded within the glucose meter. The meter uses biosensor test strips. MyHealthPoint TeleHealth Manager consists entirely of software run on a central server.	wirelessly transmit data to a remote database using standard cellular technology embedded within the glucose meter. The meter uses biosensor test strips. MyHealthPoint TeleHealth Manager consists entirely of software run on a central server.
Color	Silver	Black
LED light where the test strip is inserted	No LED Light	The LED light is to help the consumer know where to insert the test strip. Also, if they take a reading in the dark it is easier to locate where the test strip needs to be inserted.
Alarm	Yes	Same as Predicate device
Screen Display	LCD	Same as Predicate device

N. Standard/Guidance Document References

- ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus
- ISO 14971:2012, Medical Devices, Application of risk management to medical devices
- IEC 61010-1:2001, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 61010-2-101:2002, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for IVD medical equipment

O. Non-Clinical Testing

1. Test Report for IEC 61010-1/ EN61010-1 "Safety Requirements for electrical equipment for measurement, control and laboratory use.
2. FCC Test Report
3. EMC Test Report
4. Cleaning Validation Test Reports

All testing demonstrated the safety and effectiveness of the MyGlucoHealth Wireless Meter and substantial equivalence to the predicate.

P. Clinical Testing

1. Human Factor testing was conducted to evaluate the ease of use of the MyGlucoHealth Wireless Meter and ease of understanding the user manual it is paired with.

Q. Infection Control

Robustness Testing: Cleaning and disinfection can be accomplished by wiping the meter with Caviwipes XL (EPA Reg. No. 46781-8). The robustness study was conducted on three different meters and the results demonstrated that there was no change in functional

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performance or in the visual external materials of the meter after 156 cleaning and 156 disinfection cycles to simulate 3 years of use for single patient use. Each robustness cycle tested consisted of one cleaning wipe and one disinfecting wipe.

Cleaning Validation test: Disinfection efficacy/Cleaning Validation studies were performed on the materials comprising the meter by an outside testing laboratory demonstrating complete inactivation of duck hepatitis B virus with the chosen disinfectant, Caviwipes XL (EPA Registration #46781-8. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

R. Conclusion

The MyGlucoHealth Wireless System is substantially equivalent to the predicate device.